January 10, 2000). With entry of this Amendment, claim 1 has been amended to more clearly recite the claimed invention. More particularly, in order to expedite prosecution of the present case, claim 1 has been amended to recite that "if X is =O, $R^1$ is $-N(CH_3)_2$, $R^2$ is hydroxy and $R^4$ is alkyl, then $R^3$ is other than hydroxy." No new matter has been introduced by the amendment to claim 1.

In the Office Action, claims 1, 2, 5-7 and 26-27 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claims 1, 2, 5, 7, 26 and 27 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Torelli, *et al.* (U.S. Patent No. 4,634,695). Claims 1, 2, 5-7, 26 and 27 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Torelli, *et al.* Finally, claims 1,2, 4-7, 15-19 and 26 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Peeters (U.S. Patent No. 5,741,787). For the reasons set forth herein, each of these rejections is overcome.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

In the Office Action, claims 1, 2, 5-7 and 26-27 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. In making this rejection, the Examiner has stated that it is unclear what is meant by the term "cypionyloxy" as recited in the definition of "$R^2$." (*see*, page 3 of the Office Action mailed January 10, 2000).

Applicants respectfully submit that the term "cypionyloxy" is a term of art that is known to and used by those of skill in the art. Moreover, Applicants point out that the term "cypionyloxy" is, in fact, defined by the specification as originally filed. Applicants direct the Examiner's attention to page 4, lines 30-31 of the specification, wherein it is stated:

> Suitable acyloxy groups include, for example, acetoxy, *i.e.*, $CH_3COO$-, which is derived from acetic acid, formyloxy, *i.e.*, H•CO•O-, which is derived from formic acid and ***cypionyloxy, which is derived from 3-cyclopentylpropionic acid.*** (Emphasis added).

In view of the fact that cypionyloxy is a term of art used by those of skill in the art and in view of the fact that cypionyloxy is, in fact, defined in the specification as originally filed, Applicants respectfully submit that this term is definite and clear. Accordingly, Applicants urge the Examiner to withdraw the rejection under 35 U.S.C. § 112, second paragraph.

REJECTION UNDER 35 U.S.C. § 102(B):

Claims 1, 2, 5, 7, 26 and 27 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Torelli, *et al.* (U.S. Patent No. 4,634,695). In support of this rejection, the Office Action states that Torelli, *et al.* disclose compound 10, which is recited at columns 15 and 16 of the patent and which arguably falls within the scope of the claimed invention (*see*, page 4 of the Office Action mailed January 10, 2000). In addition, the Office Action states that the compounds disclosed by Torelli, *et al.* have antiprogestational and progestational activities (*see*, page 4 of the Office Action mailed January 10, 2000).

In order to expedite prosecution of the present case, Applicants have amended claim 1 to recite that "if X is =O, $R^1$ is $-N(CH_3)_2$, $R^2$ is hydroxy and $R^4$ is alkyl, then $R^3$ is other than hydroxy." As illustrated in Figure 1, for example, this particular compound is used as an intermediate to form the other compounds of interest. As such, claim 1, as amended, is ***not*** anticipated by Torelli, *et al.*

Moreover, it is pointed out that one of the advantages of the compounds of the present invention, *i.e.*, the compounds of Formula I, is that they possess potent antiprogestational activity with minimal antiglucocorticoid activity (*see*, the specification at, for example, page 1, lines 2-5; page 2, lines 19-20; and page 20, lines 20-21). In contrast to the compounds of the present invention, Torelli, *et al.* explicitly state that the compounds disclosed therein have "remarkable antiglucocorticoid properties" (*see, e.g.*, column 38, lines 55-57 of Torelli, *et al.*).

In view of the foregoing, Applicants respectfully submit that claim 1, as amended, is not anticipated by Torelli, *et al.* Accordingly, Applicants urge the Examiner to

withdraw the rejection of claims 1, 2, 5, 7, 26 and 27 under 35 U.S.C. § 102(b) over Torelli, *et al.*

REJECTION UNDER 35 U.S.C. §103 OVER TORELLI, ET AL.:

Claims 1, 2, 5-7, 26 and 27 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Torelli, *et al.* Torelli, *et al.* is cited in the Office Action for the teachings set forth above in connection with the § 102 anticipation rejection (*see*, page 5 of the Office Action mailed January 10, 2000). In addition, the Office Action alleges that although the instant invention differs from the Torelli, *et al.* reference by reciting compounds not exemplified by this reference, Torelli, *et al.* teach an equivalence between various substitutents (*see*, page 5 of the Office Action mailed January 10, 2000). Applicants respectfully ***disagree***.

It is well-settled that in considering obviousness under 35 U.S.C. § 103, the prior art as a whole must be considered and its teachings must be viewed as they would have been by one of skill in the art at the time of the invention. To properly support a rejection based upon prima facie obviousness, the Examiner must cite to a combination of prior art references which sets forth the necessary elements of the claimed invention and which provides the motivation for combining those elements to yield the claimed invention. *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 U.S.P.Q.2d 1321, 1323 (Fed. Cir. 1990). If either the necessary elements of the invention or the motivation to combine such elements is missing, the Examiner ***cannot*** properly support the rejection based upon 35 U.S.C. § 103 and it must be withdrawn.

A perusal of Torelli, *et al.* reveals that they do ***not*** teach or suggest the compounds recited in amended claim 1. As noted in the Office Action, the instant invention differs from the Torelli, *et al.* reference by reciting compounds not exemplified by the Torelli, *et al.* reference (*see*, page 5 of the Office Action mailed January 10, 2000). The only compound disclosed by Torelli, *et al.* that arguably falls within the scope of the claim 1 as originally filed is compound 10, which is recited at columns 15 and 16 of the Torelli, *et. al* patent. This is true despite the fact that Torelli, *et al.* disclose pages upon pages of compounds. As explained above, compound 10 is used in the present invention as an intermediate to form

the other compounds of interest. Moreover, it is again pointed out that compound 10 has been explicitly excluded from amended claim 1. Clearly, Torelli, *et al.* do not teach or suggest the compounds recited in amended claim 1.

Moreover, Applicants respectfully submit that Torelli, *et al.* do ***not*** provide the motivation to carry out the claimed invention, *i.e.*, to make the compounds recited in amended claim 1. As explained above, one of the advantages of the compounds of the present invention (*i.e.*, the compounds of Formula I) is that they possess potent antiprogestational activity with minimal antiglucocorticoid activity (*see*, the specification at, for example, page 1, lines 2-5; page 2, lines 19-20; and page 20, lines 20-21). In contrast to the compounds of the present invention, Torelli, *et al.* explicitly state that the compounds disclosed therein have "remarkable antiglucocorticoid properties" (*see, e.g.*, column 38, lines 55-57 of Torelli, *et al.*). As such, if one of skill in the art were interested in making compounds that possess potent antiprogestational activity with minimal antiglucocorticoid activity, the skilled artisan would stay away from the compounds and teachings of Torelli, *et al.* because again such compounds possess "remarkable antiglucocorticoid properties."

In view of the amendment to claim 1 and the foregoing remarks, Applicants respectfully submit that Torelli, *et al.* do not teach or suggest the compounds recited in amended claim 1. Absent such a teaching or suggestion, the claimed invention is non-obvious and, thus, patentable. Accordingly, Applicants urge the Examiner to withdraw the obviousness rejection under 35 U.S.C. § 103 over Torelli, *et al.*

REJECTION UNDER 35 U.S.C. § 103 OVER PEETERS:

Claims 1,2, 4-7, 15-19 and 26 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Peeters (U.S. Patent No. 5,741,787). In support of this rejection, the Office Action states that Peeters discloses a generic group of 11-substituted steroids (*see*, page 6 of the Office Action). In addition, the Office Action states that Peeters teaches that the compounds disclosed therein have antiglucocorticoid properties (*see*, page 6 of the Office Action). Although the Office Action acknowledges that the instant claims differ from the reference by reciting specific compounds not exemplified by the prior art, it nonetheless

alleges that the claims are obvious because a skilled artisan would have the reasonable expectation that any of the species of the genus would have similar properties (*see*, page 6 of the Office Action mailed January 10, 2000). Applicants respectfully ***disagree***.

A perusal of the Peeters patent reveals that Peeters does ***not*** teach or suggest the 11β-substituted-21-substituted-19-nor-progesterone analogs of the present invention. As stated in the Office Action, the instant claims differ from the reference by reciting compounds not exemplified by the prior art (*see*, page 6 of the Office Action mailed January 10, 2000). Clearly, Peeters does not teach or suggest the compounds of Formula I, *i.e.*, compounds having ***both*** a phenyl group substituted with $R^1$, wherein $R^1$ is a member selected from the group consisting of $-OCH_3$, $-SCH_3$, $-N(CH_3)_2$, $-NHCH_3$, -CHO, $-COCH_3$, and $-CHOHCH_3$, ***and*** a $-C(O)CH_2R^2$ group, wherein $R^2$ is a member selected from the group consisting of halogen, alkyl, acyl, hydroxy, alkoxy, acyloxy, alkylcarbonate, cypionyloxy, S-alkyl and S-acyl.

Moreover, Applicants respectfully submit that Peeters does ***not*** provide the motivation to carry out the claimed invention, *i.e.*, to make the compounds recited in amended claim 1. As explained above, one of the advantages of the compounds of the present invention (*i.e.*, the compounds of Formula I) is that they possess potent antiprogestational activity with minimal antiglucocorticoid activity (*see*, the specification at, for example, page 1, lines 2-5; page 2, lines 19-20; and page 20, lines 20-21). In contrast to the compounds of the present invention, Peeters explicitly states that the compounds disclosed therein are "antiglucocorticoid steroids" (*see*, *e.g.*, column 1, lines 6-8 of Peeters). In fact, the Peeters invention relates to the discovery that antiglucocorticoid steriods possess anxiolytic effects, which make such steroids useful in the treatment of anxiety disorders (*see*, column 1, lines 22-24). As such, if one of skill in the art were interested in making compounds that possess potent antiprogestational activity with minimal antiglucocorticoid activity, the skilled artisan would stay away from the compounds and teachings of Peeters because again such compounds are antiglucocorticoid steroids.

In view of the amendment to claim 1 and the foregoing remarks, Applicants respectfully submit that Peeters does not teach or suggest the compounds recited in amended

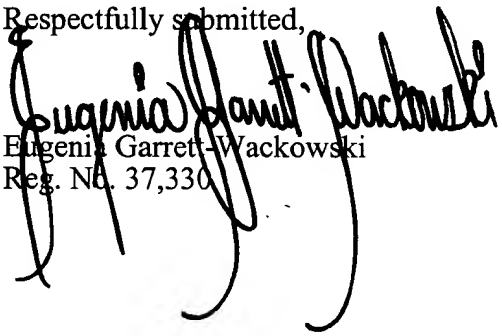
claim 1. Absent such a teaching or suggestion, the claimed invention is non-obvious and, thus, patentable. Accordingly, Applicants urge the Examiner to withdraw the obviousness rejection under 35 U.S.C. § 103 over Peeters.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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